

REMARKS

Applicants respectfully request reconsideration. Claims 46-71 were previously pending in this application with claims 46, 53, 59, and 65 being independent claims. No amendments have been made to the claims.

Applicants acknowledge the courtesies extended by Examiner Pellegrino during a telephone interview with the undersigned attorney on August 22, 2006. The substance of the interview is summarized in the remarks set forth below.

Applicants respectfully traverse each of the rejections presented in the Office Action of May 19, 2006 for reasons similar to those set forth in their prior responses of May 21, 2004 and December 23, 2003 and the declaration of Stephan N. Eldridge (hereafter the "Eldridge Declaration") submitted therewith, which are incorporated herein by reference.

Rejections Under 35 U.S.C. § 102

Rejections in View of Mulhauser

Claims 46, 47, 50, 54-56, 59-62, 65-68 and 71 stand rejected under 35 U.S.C. §102(b) as purportedly being anticipated by Mulhauser (U.S. patent No. 5,695,525). The Examiner contends that Mulhauser discloses (Figs. 4a, 4b) a surgical repair material comprising a fabric 34, a barrier layer 36 and an edge barrier 32. Applicants respectfully traverse these rejections.

As an initial matter, as explained during the interview, Mulhauser '525 is a family member of Mulhauser '246 (US 5,766,246) which was previously applied during prosecution of the claims and over which the claims were found to be patentable. Applicants respectfully assert that the claims patentably distinguish over Mulhauser '525 for at least the same reasons set forth in the prior responses.

Independent claims 46, 59 and 65 recite, *inter alia*, a prosthesis or repair fabric with an edge barrier that inhibits the formation of adhesions with tissue or organs thereto, wherein the edge barrier isolates or covers at least a portion of the edge of the fabric.

Mulhauser is directed to an implantable prosthesis 10, 30 having a mesh layer 12, 34 and a semi-rigid frame or ring 14, 32 supporting the mesh layer. (Mulhauser '525, Col. 3, lines 42-53; col. 5, lines 24-29). In the embodiment shown in Figs. 4a-4b, the fabric extends outwardly beyond the frame or ring 32 such that the frame 32 does not cover or isolate a portion of the

fabric edge. Consequently, the frame 32 is not an edge barrier as recited in the claims for at least this reason.

Nevertheless, Mulhauser does disclose a prosthesis (Figs. 2) which includes a frame that covers the edge of the mesh fabric. As shown in Figs. 2 and 3(h), the frame may be configured to extend over the mesh layer at both the peripheral edge of the mesh layer and the surface margin of the mesh layer adjacent the peripheral edge. However, as explained during the interview, Mulhauser does not teach or suggest that the frame 14, 32 has any type of adhesion inhibiting properties.

In the Office Action, the Examiner purportedly asserts that the claimed physical properties are present in the prior art material (edge barrier) to some extent even though they are not explicitly recited. (Office Action, page 3). Based on this assertion, the Examiner attempts to shift the burden to Applicants to show that the frame does not have adhesion resistant properties. (Office Action, page 3). However, as indicated during the interview, this is not the proper test for establishing a rejection based on inherency. Rather, the burden lies with the Patent Office to provide rationale or evidence that the Mulhauser frame inherently possesses the claimed adhesion resistant properties.

As explained in MPEP §2112(IV):

The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish inherency of that result or characteristic. Citing *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) (emphasis in original).

To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.' Citing *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999).

Applicants respectfully submit that the Examiner has failed to provide a rationale or evidence to establish that the Mulhauser frame is inherently adhesion resistant. Mere unsupported assertions of inherency are insufficient. Nevertheless, as discussed during the

interview, Applicants previously submitted a declaration to show that the Mulhauser frame does not inherently possess adhesion resistant properties. (See Eldridge Declaration).

Silicone or polypropylene materials, which Mulhauser discloses may be employed for the ring or frame, do not inherently or necessarily inhibit adhesions. The adhesion resistant properties of a soft tissue repair prosthesis are affected by various factors such as the surface texture and pore size of the material that forms the prosthesis or portions of the prosthesis. (See Eldridge Declaration, paragraph 9). Thus, a prosthesis may be either resistant to the formation of adhesions or promote tissue ingrowth and adhesions depending upon the particular structural characteristics of its material. (See Eldridge Declaration, paragraph 9). For example, a prosthetic material, including silicone, having a surface texture or porosity of approximately 10 μ m or more is susceptible to adhesions with tissue or muscle. (See Eldridge Declaration, paragraph 9).

Mulhauser provides no teaching or suggestion as to any structural characteristics of the frame that would determine its adhesion resistant properties. The surface texture and porosity of a silicone frame (as well as a molded polypropylene frame) can vary depending on the specific design parameters of the mold used to form the frame. (See Eldridge Declaration, paragraph 10). Therefore, a molded silicone frame can promote tissue ingrowth and adhesions with tissue and muscle. (See Eldridge Declaration, paragraph 10). Thus, simply because the Mulhauser frame may be molded from a silicone material does not necessarily provide a frame that inhibits adhesions to tissue and muscle, such that one of ordinary skill in the art would not consider the Mulhauser frame, even if formed of silicone material, as necessarily being resistant to tissue ingrowth and adhesions to tissue and muscle. (See Eldridge Declaration, paragraph 10).

In view of the foregoing, claims 46, 59 and 65 patentably distinguish over Mulhauser, such that the rejections under §102 should be withdrawn. Mulhauser does not disclose an adhesion resistant edge barrier as recited in each of the claims.

Claims 47 and 50, claims 60-62, and claims 66-68 and 71 respectively depend from claims 46, 59 and 65 and are patentable for at least the same reasons. It is unclear as to the basis for the rejection of claims 54-56 as they depend from claim 53 which has not been rejected in view of Mulhauser. Nevertheless, claim 53, which also recites an edge barrier, patentably distinguishes over Mulhauser for at least the same reasons as independent claims 46, 59 and 65,

and claims 54-56 are patentable for at least the same reasons. Accordingly, withdrawal of these rejections is respectfully requested.

Rejections in View of Meier

Claims 53, 56, 65, 68 and 71 stand rejected under 35 U.S.C. §102(b) as purportedly being anticipated by Meier (U.S. patent No. 3,416,524). The Examiner contends that Meier shows (Fig. 2) a surgical repair material comprising a fabric 15, a barrier layer 14 and an edge barrier 12. Applicants respectfully traverse these rejections.

As indicated above, independent claims 53 and 65 recite, *inter alia*, a prosthesis or repair fabric with an edge barrier that inhibits the formation of adhesions with tissue or organs thereto, wherein the edge barrier isolates or covers at least a portion of the edge of the fabric.

Meier is directed to a non-adherent surgical dressing including a laminated pad 13 with a cellulosic layer 14 and a resin fiber layer 15 which are joined by needled resin fibers 16 using a needling and heat fusion process. The cellulosic layer has moisture absorption properties while the resin fiber layer has a porous surface which serves as the non-adherent contact surface for the wound and which permits free flow to moisture. The pad is surrounded by an edge frame or crown 12 which stabilizes the edges of the cellulosic layer and the resin fiber layer.

As discussed during the interview, Meier does not teach or suggest that the frame has any type of adhesion inhibiting properties. Rather, Meier discloses that frame provides freedom from fraying, loose fibers, delamination and the like by surrounding and stabilizing the edges of the cellulosic layer and the resin fiber layer. (Col. 2, lines 51-56). Meier indicates that the frame may be fabricated from any of a variety of materials, such as an inert thermoplastic substance, which is sufficiently flexible for purposes of being applied with the pad to curved body surfaces and yet which affords sufficient rigidity to stabilize the pad and prevent delamination, etc. (Col. 2, line 67 to Col. 3, line 2).

As explained above in connection with Mulhauser, the adhesion resistant properties of a soft tissue repair prosthesis are affected by various factors including the surface texture and pore size of the material that forms the prosthesis or portions of the prosthesis. Thus, a prosthesis may be either resistant to the formation of adhesions or promote tissue ingrowth and adhesions depending upon the particular structural characteristics of its material. As discussed above, a

prosthetic material having a surface texture or porosity of approximately 10 μ m or more is not adhesion resistant, but rather is susceptible to adhesions with tissue or muscle.

Meier provides no teaching or suggestion as to any structural characteristics of the frame that would allow one of ordinary skill in the art to determine its adhesion resistant properties. Although Meier discloses that the frame may be formed from any of various materials, Meier is silent as to the surface texture and porosity of the frame, such that one of ordinary skill in the art would not consider the Meier frame as necessarily being resistant to tissue ingrowth and adhesions to tissue and muscle. Thus, Meier does not disclose an edge barrier that inhibits the formation of adhesions with tissue and organs thereto.

In view of the foregoing, claims 53 and 65 patentably distinguish over Meier, such that the rejections under §102 should be withdrawn. Meier fails to at least disclose an adhesion resistant edge barrier as recited in each of the claims.

Claim 56 and claims 68-71 respectively depend from claims 53 and 65 and are patentable for at least the same reasons.

Rejections Under 35 U.S.C. § 103

Claims 48, 49, 51, 52, 57, 58, 63, 64, 69 and 70 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Mulhauser '525 in view of Gianturco (US 5,258,000). Applicants respectfully traverse these rejections.

Without acceding to the propriety of the combination as suggested by the Examiner, claims 48, 49, 51 and 52 depend from claim 46 and are patentable for at least the same reasons set forth above. Similarly, claims 57 and 58 depend from claim 53 and are patentable for at least the same reasons set forth above; claims 63 and 64 depend from claim 59 and are patentable for at least the same reasons set forth above; and claims 69 and 70 depend from claim 65 and are patentable for at least the same reasons set forth above. Accordingly, withdrawal of these rejections is respectfully requested.

Double Patenting

Claims 46-58 and 65-71 stand rejected under the judicially created doctrine of obviousness-type double patenting over claims 24 and 35-39 of U.S. Patent 6,258,124.

Without acceding to the propriety of the double patenting rejection, Applicants submit herewith a Terminal Disclaimer to advance prosecution of this application. However, the filing of the Terminal Disclaimer is not an admission by Applicants that the claims of the present application are obvious in view of the claims of the '124 patent.

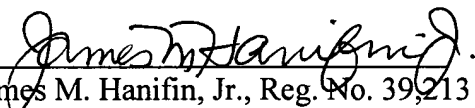
In view of the foregoing, the rejections of claims 46-58 and 65-71 under the doctrine of obviousness-type double patenting should be withdrawn.

CONCLUSION

In view of the foregoing remarks, this application should now be in condition for allowance. A notice to this effect is respectfully requested. If the Examiner believes, after this amendment, that the application is not in condition for allowance, the Examiner is requested to call the undersigned attorney at the telephone number listed below.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicants hereby request any necessary extension of time. If there is a fee occasioned by this response, including an extension fee, that is not covered by an enclosed check, please charge any deficiency to Deposit Account No. 23/2825.

Respectfully submitted,

By: 
James M. Hanifin, Jr., Reg. No. 39,213
WOLF, GREENFIELD & SACKS, P.C.
600 Atlantic Avenue
Boston, Massachusetts 02210-2211
Telephone: (617) 720-3500

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